

NIH POLICY MANUAL

54511 - PROJECT SITE VISITS INVOLVING REVIEW OF GRANT AND COOPERATIVE AGREEMENT APPLICATIONS

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A. Purpose

This chapter states the NIH policy and establishes procedures for project site visits involving grant and cooperative agreement applications, hereafter both referred to as grant applications.

B. Applicability

This policy and implementing procedures are applicable to project site visits conducted as a part of the review of NIH grant applications.

C. Background

Project site visits provide valuable information and assistance to reviewers. Some of the benefits to NIH are explained below.

Direct discussion with the principal investigator and associates can provide reviewers with an evaluation of the participants' research experience, knowledge of the research field, commitment to the project, and exact functions and interrelationships of other investigators. Such discussions are especially valuable with a principal investigator or critical associate entering a new or newly developing research field.

Reviewers can assess the quality of certain physical facilities, laboratories, or specific equipment to assure their adequacy for the proposed research.

In discussions with administrative personnel, the reviewers can evaluate the institutional commitment to a project, the availability of space, the need for a requested piece of equipment, and long-range plans for staffing and program development.

Reviewers can observe and discuss particular techniques, experimental preparations, unusual items of equipment or proposed procedures.

For institutional training grant applications, reviewers can interview trainees and assess the training staff and environment.

D. References

1. NIH Manual Chapter [4510](#), Referral and Initial Review of NIH Grant and Cooperative Agreement Applications.
2. NIH Manual Chapter [4513](#), Review of NIH Programs and Grant and Cooperative Agreement Applications by National Advisory Councils and Boards.
3. Handbook for Executive Secretaries, prepared by the Scientific Review Branch, Division of Research Grants (DRG).

E. Policy

1. It is NIH policy to obtain the most competent advice in the initial review of competing grant applications (Types 1, 2, 3, and 9). As with regularly appointed Initial Review Group (IRG) members, site visitors are chosen from those best qualified with respect to experience, capability, and recognized achievement in relevant fields; for their mature judgment and objectivity; and for their ability and availability to participate adequately and in an unbiased manner in the review deliberations. Every effort is made to avoid both the fact and the appearance of conflict of interest in obtaining the advice necessary for scientific and technical merit review.
2. Qualified women, ethnic minorities, and the handicapped should be considered for involvement as site visitors.
3. The Executive Secretary, with the approval of his or her supervisor, and in consultation with the Chairman of the IRG and others, is the staff person responsible for judging the need for a site visit, determining finally the scientific disciplines to be represented, compiling names of scientists with qualifications needed for adequate scientific review, and selecting and contacting individual scientists to serve as members of the site visit team. Business management consultants will be added where needed.

F. Implementation

1. *Determining Need for a Site Visit --*

NIH Executive Secretaries shall regularly seek the advice of IRG members, and as appropriate, program and grants management staff regarding the need for a site visit.

The assigned IRG reviewers of an application may also identify a need for a project site visit prior to an upcoming IRG meeting. In this case, the Executive Secretary should be informed of the reasons for this request and determine its

validity.

2. *Situations for Site Visiting --*

Project site visits may be made under the following circumstances when necessary:

when it is needed to provide adequate review, as might be the case with large multifaceted types of applications;

when an application has been recommended for deferral by an IRG (usually this is because the IRG does not have enough information from the application to arrive at a definitive recommendation of approval or disapproval) and the needed information cannot satisfactorily be obtained through correspondence or by telephone; or

when a National Advisory Council or Board does not concur with the recommendation of the IRG and wishes additional information that can only be obtained by a site visit.

A site visit is not to be made for the purpose of improving an applicant's chances for approval. It is the applicant's responsibility to submit as sufficiently and satisfactorily complete an application as possible. If the needed information can be obtained by mail, the applicant is not site visited. Site visits are not automatic for any type of application, even for large, multifaceted applications, but are made in each instance because on-site discussion and observation are the only means of obtaining the desired information.

3. *Procedure*

a. *Notification*

The applicant institution and investigator must be notified by the Executive Secretary that a project site visit will be organized. If the site visit will alter the timing of the normal review cycle, the applicant will be advised.

b. *Selection of Site Visitors*

(1) The Executive Secretary selects the most appropriately qualified reviewers to make the visit.

-- To the extent possible, current IRG members should make the site visits, but special (ad hoc) reviewers may

be used if there is need for additional expertise or if appropriate IRG members are not available.

-- For a regular research project grant application (R01), where there is generally a single scientific focus or objective, two or three individuals are normally adequate for evaluating the proposed research.

-- For large, complex, multifaceted program projects, centers, or projects involving consortium arrangements, a larger site visit team may be needed.

-- The need for services of a business management consultant should be determined by assessing the organizational or administrative complexity of the application. Expert management advice may be essential for adequate review. The Executive Secretary should seek advice from the BID Grants Management Officer in determining the need for business management consultants. (In the review of R01 applications, the use of business management consultants as review team members is not usually considered necessary. Special circumstances may, however, warrant exception to this general rule.)

(2) The Executive Secretary should not ask or accept suggestions from the principal investigator for potential site visitors. However, in some instances, it may be useful to discuss with the investigator the specific disciplines or specialty areas of expertise which the investigator feels are required to review the application properly. Also, prior to inviting reviewers to participate in a site visit, the Executive Secretary may ask the investigator if, in his or her opinion, there are individuals who may not be able to give an unbiased review and who therefore should not be invited. Full consideration should be given to valid reasons presented by the investigator for requesting that a particular scientist not be invited.

Program Staff (and grants management staff when business consultants are used) may suggest names of potential site visitors for consideration by the Executive Secretary but shall not be otherwise involved in the selection of the site visit team, unless invited to do so by the Executive Secretary. BID program staff should not contact the principal investigator nor actual or potential site visitors about the composition of the site visit team.

The Executive Secretary's invitation to serve on a site visit team will be withdrawn only under exceptional circumstances and then following

consultation with and agreement by his or her supervisor.

c. NIH Staff Attending Site Visits

The Executive Secretary should invite BID program staff to attend the site visit. The Grants Management Officer shall participate with the appropriate BID staff in determining the advisability of having grants management staff also accompany the review team as a staff resource. Program and grants management staff participating in a project site visit may serve as staff resources to the site teams but may not participate in evaluations or recommendations.

Usually no more than one program staff representative from any given BID attends a site visit. If the application has been dually assigned, representatives from both BIDs may be invited to attend as observers. If the BID requests that a fiscal or grants management staff member also attend, the limitation of one or two BID observers may be waived.

d. Preparation of Site Visit Reports

Written project site visit reports must be prepared unless the visit immediately precedes the IRG meeting.

Different approaches may be used for preparing a project site visit report: (1) one or more of the site visitors may be designated to write the entire report in final or draft form; or (2) each visitor may be asked to write an individual section, after which the various parts are assembled by the Executive Secretary or one of the site visitors in final or draft form. In the case of large complex, multifaceted applications, coverage on various aspects of the application may be assigned to members of the site visit team to prepare a draft report at the site. The report is discussed by the site visit team prior to their departure from the site to assure that it is accurate, complete, and acceptable to the site visitors. Any business management consultant's written report should be summarized by the Executive Secretary and made a part of the summary statement.

The site visit report is a working document that provides additional substantive information for the IRG when it discusses and evaluates the application and arrives at a recommendation. Once the information in the site visit report is incorporated into the summary statement, it should be destroyed.

e. Organization and Conduct of Site Visits

Details relevant to the organization, conduct, and report of a project site visit can be found in the DRG Handbook for Executive Secretaries. In

addition, individual BIDs may formulate specific guidelines, especially for site visits to applicants for program project, center, and other specialized grant applications.

G. Effective Date

This policy is effective on date of release.

H. Additional Information

For further information on this manual chapter, contact: Office of Extramural Research and Training, OD, 496-2241 or the Division of Research Grants, 496-7248.

For copies of this manual chapter send a form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07; or call the Office of Extramural Research and Training, 496-5967.